

Code: 17S10101

M.Pharm I Semester Regular Examinations February 2018

**PHARMACEUTICAL PRODUCT DEVELOPMENT & TECHNOLOGY TRANSFER**

(Pharmaceutical Technology)

(For students admitted in 2017 only)

Time: 3 hours

Max. Marks: 60

Answer all the questions

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- 1 Give an account on regulations for filing IND according to USFDA.  
**OR**
- 2 Write a note on CDSCO guidelines for:
  - (a) SUPAC.
  - (b) BACPAC.
- 3 Give a detailed account on the protocol of preformulation studies.  
**OR**
- 4 Write about the following:
  - (a) Co-solvency.
  - (b) pH – Solubility profiles.
  - (c) Significance of micromeritic properties in tablet compression.
- 5 Explain about large scale manufacturing techniques of suspensions.  
**OR**
- 6 (a) What is the significance of pilot plant scale up studies? Illustrate the layout of pilot plant scale up studies.  
(b) Give a brief account on scale up of wet granulation technique.
- 7 Write a detailed account on various types of plastic materials used for packaging. Add a note on drug – plastic interactions and measures to prevent them.  
**OR**
- 8 Give an account on:
  - (a) Types of glass as packaging material.
  - (b) Quality control tests for packaging material.
- 9 Write a detailed note on development of technology by R & D.  
**OR**
- 10 Explain about documentation involved in technology transfer and exhibit.

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